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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/504,280	02/15/2000	Mike A. Clark	phoe-0057	5368

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EXAMINER	
ROMEO, DAVID S	
ART UNIT	**PAPER NUMBER**
1647	17

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/504,280	CLARK, MIKE A.	
	Examin r	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on th cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,14-17 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,14-17 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-8,14-17 and 24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 7, 2003 has been entered.

Claims 1-8, 14-17, 24 are pending. Applicant's election with traverse of group II and the species succinimidyl succinate in Paper No. 7 is acknowledged. Applicant timely traversed the restriction (election) requirement in Paper No. 7. Claims 1-8, 14-17, 24 are being examined to the extent that they read upon the elected invention and/or species.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Although modification of TNF-α with 5-, 12-, or 20-kDa PEG is supported by the 60/035,521 application, the 60/035,521 application does not support any of the other

embodiments of the present claims. Should applicant disagree, it is incumbent upon applicant to specifically point out the specific disclosure in the 60/035,521 application which specifically supports each and every claim limitation in all the pending claims.

New formal matters, objections, and/or rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 14-17, 24 are rejected under 35 U.S.C. 102(a or b) as being anticipated by Tsutsumi (u17).

This rejection is being made under 35 U.S.C. 102(b) because, although modification of TNF-α with 5-, 12-, or 20-kDa PEG is supported by the 60/035,521 application, the 60/035,521 application does not support any of the other embodiments of the present claims.

This rejection is being made in the alternative under 35 U.S.C. 102(a) in the event that the 60/035,521 application specifically supports each and every specific claim limitation in all the pending claims.

Tsutsumi discloses the modification of human TNF-α with PEG with a number-average molecular weight of 12,000 via the formation of an amino bond between lysine amino groups of TNF-α and the terminal succinimidyl succinate group of PEG. The coupling reaction between

TNF-α and $PEG_{12,000}$ was remarkably limited, and the maximal degree of PEG modification was 36%, probably caused by the steric hindrance derived from $PEG_{12,000}$. When PEG-TNF-αs were the same molecular size, the TNF-α modified with higher molecular weight PEG had a higher bioactivity than when modified with lower molecular weight PEG (page 1091, paragraph bridging left and right columns). The 36% maximal degree of PEG modification is "between about five and twelve PEG molecules" in the absence of evidence to the contrary. PEG with a number-average molecular weight of 12,000 is "PEG" "where said PEG has an *approximate* weight average molecular weight in the range of *about* 20,000 to about 30,000," (italics added) in the absence of evidence to the contrary. The limitation "recombinant" is viewed as a product-by-process limitation. Although Tsutsumi does not describe the recombinant production of TNF-α, the recitation of a "recombinant" process limitation is not viewed as positively limiting the TNF-α absent a showing that the "recombinant" process imparts a novel or unexpected property to the TNF-α, as it is assumed that equivalent products are obtainable by multiple routes. The burden is upon the applicants to establish a patentable distinction between Tsutsumi's TNF-α and "recombinant" TNF-α. Tsutsumi believes that $PEG_{12,000}$-TNF-α Fr.3 has a markedly prolonged plasma half-life, resulting in an increase in the anti-tumor potency (page 1094, left column). Further, chemical modification of bioactive proteins with PEG results in augmented plasma half-lives and stability and increases therapeutic potency, thereby enabling therapeutic dose and frequency to be decreased (page 1090, left column). The modification of TNF-α with PEG_{5000} effectively reduced its systemic toxic side effects (page 1090, right column) and a single intravenous administration of $PEG_{12,000}$-TNF-α Fr.3 induced marked anti-tumor effects without TNF-α-mediated side-effects (page 1094, right column). In any case, the

recitation of "enhancing the circulating half life of TNF while reducing its toxicity" and "enhancing the tumoricidal activity of TNF" occurs in the claim preamble and is an intended use of the claimed method. The intended use of the claimed method does not distinguish such a method from Tsutsumi's method. The intended use does not result in a manipulative difference as compared to the prior art. The intended use has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process and the body of the claim does not depend on the preamble for completeness but, instead, the process steps are able to stand alone.

Claim Rejections - 35 USC § 103

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsutsumi (u17) and Mark (v17).

Tsutsumi discloses the modification of human TNF-α with PEG with a number-average molecular weight of 12,000 via the formation of an amino bond between lysine amino groups of TNF-α and the terminal succinimidyl succinate group of PEG. The coupling reaction between TNF-α and $PEG_{12,000}$ was remarkably limited, and the maximal degree of PEG modification was 36%, probably caused by the steric hindrance derived from $PEG_{12,000}$. When PEG-TNF-αs were the same molecular size, the TNF-α modified with higher molecular weight PEG had a higher bioactivity than when modified with lower molecular weight PEG (page 1091, paragraph bridging left and right columns). The 36% maximal degree of PEG modification is "between about five and twelve PEG molecules" in the absence of evidence to the contrary. PEG with a number-average molecular weight of 12,000 is "PEG" "where said PEG has an *approximate*

weight average molecular weight in the range of *about* 20,000 to about 30,000," (italics added) in the absence of evidence to the contrary. The limitation "recombinant" is viewed as a product-by-process limitation. Although Tsutsumi does not describe the recombinant production of TNF-α, the recitation of a "recombinant" process limitation is not viewed as positively limiting the TNF-α absent a showing that the "recombinant" process imparts a novel or unexpected property to the TNF-α, as it is assumed that equivalent products are obtainable by multiple routes. The burden is upon the applicants to establish a patentable distinction between Tsutsumi's TNF-α and "recombinant" TNF-α. Tsutsumi believes that $PEG_{12,000}$-TNF-α Fr.3 has a markedly prolonged plasma half-life, resulting in an increase in the anti-tumor potency (page 1094, left column). Further, chemical modification of bioactive proteins with PEG results in augmented plasma half-lives and stability and increases therapeutic potency, thereby enabling therapeutic dose and frequency to be decreased (page 1090, left column). The modification of TNF-α with PEG_{5000} effectively reduced its systemic toxic side effects (page 1090, right column) and a single intravenous administration of $PEG_{12,000}$-TNF-α Fr.3 induced marked anti-tumor effects without TNF-α-mediated side-effects (page 1094, right column). In any case, the recitation of "enhancing the circulating half life of TNF while reducing its toxicity" and "enhancing the tumoricidal activity of TNF" occurs in the claim preamble and is an intended use of the claimed method. The intended use of the claimed method does not distinguish such a method from Tsutsumi's method. The intended use does not result in a manipulative difference as compared to the prior art. The intended use has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process and the body of the claim does not depend on the

preamble for completeness but, instead, the process steps are able to stand alone. Tsutsumi does not teach the modification of human TNF-α with PEG with a number-average molecular weight of 12,000, wherein said TNF is human TNF mutated by deleting amino acids 1-9 of the mature TNF protein.

Mark teaches that human TNF mutated by deleting amino acids 1-9 of the mature TNF protein has the same biological activity as mature TNF (page 413, Table II). Mark does not teach the modification of human TNF-α with PEG with a number-average molecular weight of 12,000, wherein said TNF is human TNF mutated by deleting amino acids 1-9 of the mature TNF protein.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to modify human TNF-α with PEG with a number-average molecular weight of 12,000, as taught by Tsutsumi, and to modify that teaching by modifying human TNF-α with PEG with a number-average molecular weight of 12,000, wherein said TNF is human TNF mutated by deleting amino acids 1-9 of the mature TNF protein, as taught by Mark, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because a smaller peptide with the same biological activity of a larger peptide would require a smaller net amount on a mole per mole basis for administration.

The invention is prima facie obvious over the prior art.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 14-17, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsutsumi (AL, cited by Applicants) in view of Satake-Ishikawa (y17) and Ishikawa (n17).

Tsutsumi teaches the pegylation of natural human TNF-α with N-succinimidyl succinate PEG via the formation of an amide bond between a lysine amino acid residue of TNF-α and the succinimidyl succinate group, wherein the PEG has a molecular weight of about 5,000 (page 9, column 2, full paragraph 1; page 10, column 2, full paragraph 1). The amide bond between a lysine amino acid residue of TNF-α and the succinimidyl succinate group is a covalent bond that binds the TNF to the PEG through primary amines on the TNF. The succinimidyl succinate group is a biocompatible linker. The pegylation enhanced the circulating half life and tumoricidal activity of the TNF in mice suffering from a tumor (Abstract; page 9, paragraph bridging columns 1-2; page 10, column 1, full paragraph 1; Figures 1 and 2). MPEG-TNF-α induced tumor regression without any TNF-α-mediated side-effects (sentence bridging pages 1186-1187). Tsutsumi does not teach the modification of TNF with PEG(20,000).

Satake-Ishikawa discloses that modification with a larger PEG molecule is more effective to enhance the in vivo activity of rHuG-CSF and exemplifies this teaching with PEG(10,000) (Abstract).

Ishikawa discloses the modification of G-CSF with PEG (page 5, full paragraph 3). A molecular weight of the PEG used is from 500-20,000 (page 5, full paragraph 4).

Satake-Ishikawa and Ishikawa do not teach the modification of TNF.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to modify TNF-α with PEG(5000), as taught by Tsutsumi, and to modify

that teaching by using PEG(20,000), as taught by Ishikawa, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because a larger PEG molecule is more effective to enhance in vivo activity.

Any modification of TNF-α with PEG is "between about five and twelve PEG molecules" in the absence of evidence to the contrary. The limitation "recombinant" is viewed as a product-by-process limitation. Although Tsutsumi does not describe the recombinant production of TNF-α, the recitation of a "recombinant" process limitation is not viewed as positively limiting the TNF-α absent a showing that the "recombinant" process imparts a novel or unexpected property to the TNF-α, as it is assumed that equivalent products are obtainable by multiple routes. The burden is upon the applicants to establish a patentable distinction between Tsutsumi's TNF-α and "recombinant" TNF-α. In any case, the recitation of "enhancing the circulating half life of TNF while reducing its toxicity" and "enhancing the tumoricidal activity of TNF" occurs in the claim preamble and is an intended use of the claimed method. The intended use of the claimed method does not distinguish such a method from Tsutsumi's method. The intended use does not result in a manipulative difference as compared to the prior art. The intended use has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process and the body of the claim does not depend on the preamble for completeness but, instead, the process steps are able to stand alone.

The invention is prima facie obvious over the prior art.

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsutsumi (AL, cited by Applicants) in view of Satake-Ishikawa (y17) and Ishikawa (n17) as applied to claim 1 above and further in view of Mark (v17).

Tsutsumi in view of Satake-Ishikawa and Ishikawa teach the modification of TNF-α with PEG(20,000), as discussed above. Tsutsumi in view of Satake-Ishikawa and Ishikawa do not teach the modification of human TNF-α with PEG(20,000), wherein said TNF is human TNF mutated by deleting amino acids 1-9 of the mature TNF protein.

Mark teaches that human TNF mutated by deleting amino acids 1-9 of the mature TNF protein has the same biological activity as mature TNF (page 413, Table II). Mark does not teach the modification of human TNF-α with PEG(20,000), wherein said TNF is human TNF mutated by deleting amino acids 1-9 of the mature TNF protein.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to modify TNF-α with PEG(20,000), as taught by Tsutsumi in view of Satake-Ishikawa and Ishikawa, and to modify that teaching by modifying human TNF-α with PEG(20,000), wherein said TNF is human TNF mutated by deleting amino acids 1-9 of the mature TNF protein, as taught by Mark, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because a smaller peptide with the same biological activity of a larger peptide would require a smaller net amount on a mole per mole basis for administration.

The invention is prima facie obvious over the prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 14-17, 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modification of TNF-α with PEG having an approximate weight average molecular weight in the range of 10,000 to about 40,000, does not reasonably provide enablement for modification of TNF-α with 5-12 PEG molecules having an approximate weight average molecular weight in the range of 10,000 to about 40,000. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The claims are directed to or encompass the modification of mature human TNF-α with 5-12 PEG molecules having an approximate weight average molecular weight in the range of 10,000 to about 40,000. The only working examples in the present specification that are commensurate with modification of TNF-α with "PEG molecules having an approximate weight average molecular weight in the range of 10,000 to about 40,000" show the modification of TNF-α through the primary amines of TNF-α. See Table 1 on page 10. However, Tsutsumi (u17) discloses that the coupling reaction between TNF-α and $PEG_{12,000}$ was remarkably limited, and the maximal degree of PEG modification was 36%. This phenomena was also observed with a longer reaction time and a higher concentration of $PEG_{12,000}$ relative to TNF-α and was probably caused by the steric hindrance derived from $PEG_{12,000}$. See Tsutsumi (u17) at page 1091, paragraph bridging left and right columns. Furthermore, in mature human TNF-α there are only seven primary amines (six

lysines plus the amino terminus). Clearly, the modification of more than seven primary amines is impossible and the maximal degree of PEG modification of TNF-α through primary amines is limited to 36%. The specification lacks guidance for, and working examples of, the modification of mature TNF-α with 5-12 PEG molecules having an approximate weight average molecular weight in the range of 10,000 to about 40,000. The skilled artisan is left to unduly extensive, random, trial and error experimentation in order to determine how to make the claimed invention. Moreover, modification of TNF-α with 5-12 PEG molecules encompasses the modification of all the lysines in TNF-α. Extensive PEG modification of TNF-α results in the complete loss of bioactivity in vitro, suggesting that PEG chains sterically inhibit TNF-receptor binding. See Tsutsumi (w17) at page 966, full paragraph 1. Thus, although one may be able to increase the circulating half-life and decrease the toxicity of TNF-α by extensive PEG modification, this increase in the circulating half-life of TNF-α would not enhance the tumoricidal activity of TNF that had completely lost bioactivity. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 14-17, 24 are indefinite because they recite the term "TNF". The present specification defines "TNF" as various TNF mutant proteins and TNF proteins that have been mutated by amino acid deletion or alteration. See pages 5-6. Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "TNF" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Claim Objections

Claim 17 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A molecule having an "approximate weight average molecular weight in the range of about 20,000 to about 30,000" (claim 17) does not further limit a molecule having an "approximate molecular weight in the range of 20,000 to 30,000" (claim 16).

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
JULY 12, 2003